K051267

JUN 15 2005

510(K) Summary of Safety and Effectiveness

1. **Applicant Name, Address:** W.L. Gore & Associates, Inc.
3450 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 86002-0900

Contact Person: Jacqueline Kalbach
(928)864-3731

Date of Summary: May 12, 2005

2. **Classification Name:** Resorbable Barrier Membrane

Common or Usual Name: Regenerative Material

Proprietary Names:

GORE RESOLUT® Regenerative Material, GORE RESOLUT® XT Regenerative Membrane, GORE OSSEOQUEST Regenerative Membrane, GORE RESOLUT® ADAPT Regenerative Membrane, and GORE RESOLUT® ADAPT LT Regenerative Membrane

3. **Predicate Devices**:

BIO-GIDE® Resorbable Bilayer Membrane (K960724), BIOBAR Biodegradable Collagen Membrane (K001598), and Collagen Dental Membrane (K011695).

4. **Device Description**:

These devices are composed of synthetic resorbable copolymers and have been designed to act in accordance with the accepted principles of wound healing and regenerative therapy. Specifically, the membranes are designed to be biocompatible, separate tissue (cell occlusive), clinically manageable, and allow for tissue integration. The fifth requirement for regenerative therapy is spacemaking, and bone grafting or bone filling materials may be used in conjunction with the membranes to assist in providing the space necessary for regenerative healing.

5. **Intended Use:**

The indication for use will be expanded for each applicant device to include the following: "It is intended for use during the process of guided bone regeneration as a bioabsorbable membrane for supporting: immediate augmentation around implants (e.g., dehiscence and fenestration defects, extraction sockets); ridge augmentation for later implantation of endosseous implants; and sinus procedures (e.g., sinus window, sinus lift)."

6. **Technological Characteristics:**

The applicant devices are composed of synthetic resorbable materials and the predicate devices are composed of resorbable collagen. The applicant and predicate devices have been designed to act in accordance with the accepted principles of wound healing and regenerative therapy.

7. **Assessment of Performance Data:**

A preclinical *in vivo* study was conducted to evaluate the ease of use, clinical performance, and efficacy of the synthetic resorbable membranes as compared to the predicate device, BIO-GIDE® Resorbable Bilayer Membrane. In this study, new bone formation in ridge defects treated with the synthetic resorbable membranes was statistically equivalent to or better than bone formation with the predicate device.

Results from human studies reported in the literature for both synthetic resorbable membranes and resorbable collagen membranes are consistent with the preclinical *in vivo* study. Both types of resorbable materials are effective as a barrier to aid in wound healing and regenerate bone around defects associated with dental implants, and for ridge augmentation and sinus procedures.

8. **Conclusion:**

GORE RESOLUT Regenerative Material, GORE RESOLUT XT Regenerative Membrane, GORE OSSEOQUEST Regenerative Membrane, GORE RESOLUT ADAPT Regenerative Membrane, and GORE RESOLUT ADAPT LT Regenerative Membrane are substantially equivalent to the predicate devices and may be used during the process of guided bone regeneration as a bioabsorbable membrane for supporting: immediate augmentation around implants (e.g., dehiscence and fenestration defects, extraction sockets); ridge augmentation for later implantation of endosseous implants; and sinus procedures (e.g., sinus window, sinus lift).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2007

Ms. Jacqueline Kalbach
Regulatory Affairs Associate
W.L. Gore & Associates, Incorporated
3450 West Kiltie Lane
P.O. Box 500
Flagstaff, Arizona 86002-0900

Re: K051267
Trade/Device Name: GORE RESOLUT® Regenerative Material, GORE RESOLUT® XT Regenerative Membrane, GORE OSSEOQUEST Regenerative Membrane, GORE RESOLUT ADAPT Regenerative Membrane, and GORE RESOLUT® ADAPT LT Regenerative Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: May 12, 2005
Received: May 16, 2005

Dear Ms. Kalbach:

This letter corrects our substantially equivalent letter of June 15, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 http://www.fda.gov/cdrh/organiz.html#OC for OC organization structure). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051267

Statement of Intended Use

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510(k) Number (if known) K051267

Device Name:

GORE RESOLUT® Regenerative Material, GORE RESOLUT® XT Regenerative Membrane, GORE OSSEOQUEST Regenerative Membrane, GORE RESOLUT® ADAPT Regenerative Membrane, and GORE RESOLUT® ADAPT LT Regenerative Membrane

INDICATIONS FOR USE:

The following will be added to the current indications for use statement for each of the devices listed above:

> It is intended for use during the process of guided bone regeneration as a bioabsorbable membrane for supporting: augmentation around immediately placed endosseous implants or existing endosseous implants (e.g., dehiscence and fenestration defects, extraction sockets); ridge augmentation for later implantation of endosseous implants; and sinus procedures (e.g., sinus window, sinus lift).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use J **OR** **Over-The-Counter Use** ___
(per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K051267

(Optional Format 1-2-96)